REMARKS

1. Status of the Claims

Claims 1, 4-13 and 16 are currently pending. Applicant has cancelled claims 2-3 and 14-15 as being directed to a non-elected invention but reserve their right to pursue these claims in a divisional application.

2. Drawings

The Drawings have been objected to because of copy marks and because the lines, numbers were not uniformly thick and well defined. Applicant hereby enclosed a replacement set of drawings. Reconsideration and removal of the objection is respectfully requested.

3. Claim Objections

The Examiner has objected to certain informalities in claims 1, 11 and 13. Claim 1 was objected to because the phrase "which is genetically modified" was redundant. This phrase has been removed. Claim 11 was objected to because the claim did not end in a period. The appropriate punctuation has been inserted. And, claim 13 was objected to because of improper multiple dependency. Claim 13 has been amended to overcome the improper multiple dependency objection. Reconsideration and removal of the objections is respectfully requested.

4. Claim Rejections under 35 U.S.C. §112, second paragraph

Claims 1, 4-13 and 16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner has rejected claims 1 and 10 because certain phrases such as "by means of introduction of" and "whose presence or expression leads to" were not sufficiently clear. The Examiner also rejected claims 5, 8 and 11 for the use of the phrase "and/or". Applicant has amended the claims to address these issues and believes that the amendments have obviated these rejections. New claims 17-19 have been added and contain the subject matter removed from claims 5 and 11. No new matter has been added.

Applicant has not, however, replaced the phrase "foreign nucleic acid molecule" with "heterologous cDNA" as suggested by the Examiner. The Examiner argues that this phrase is indefinite because it does not indicate whether the foreign nucleic acid molecule is coding, non-coding or regulatory. First, Applicant would like to point out that this term is adequately described by the Specification on page 3, last paragraph. Second, Applicant would like to point out the use of the phrase foreign nucleic acid molecule in this context is generally accepted by the USPTO. Moreover, Applicant submits that restricting the term to encompass only cDNAs would be inappropriate and misleading. A genomic nucleic acid molecule containing introns may also encode an ATP/ADP translocator. Moreover, with respect to bacteria, bacterial cDNA libraries are not usually prepared and genomic libraries are used because bacterial cDNAs do not contain introns and the lack of poly-A tails makes it difficult to prepare mRNA. For the reasons set forth above, Applicant submits that the meaning and scope of the term would be readily apparent to a person of ordinary skill in the art and, as such, is not indefinite. Accordingly, reconsideration and removal of the rejections is respectfully requested.

5. Claim Rejections under 35 U.S.C. §112, first paragraph

The Examiner has rejected claims 1, 4-13 and 16 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner argues that Applicant has not provided adequate written description support for the claimed invention as the Specification only describes two foreign nucleic acid molecules. The Examiner has also rejected these claims for lack of enablement. The Examiner argues that the Specification only describes a method of producing transgenic potato plants transformed with the AATPI-cDNA gene from *Arabidopsis* exhibiting an increased yield of starch and percent amylose content. The Examiner further argues that the Specification does not enable a method for producing transgenic plants transformed with "a foreign nucleic acid molecule of undefined source, length, and function which exhibits an increased yield of starch and percent amylose content. Applicant respectfully traverses.

A. Written Description

The Examiner points out that the claims are directed to the use of a foreign nucleic acid molecule of unspecified length, source and function and that the Specification only describes two cDNAs which encode the AATP2 ADP/ATP translocator from *Arabidopsis* and the AATP1 from *S. tuberosum*. The Examiner has argued that the Specification does not provide adequate written support for the use of any foreign nucleic acid molecule. Applicant disagrees. The test for whether the Specification provides adequate written description support for the claimed invention is whether the application reasonably conveys to the artisan that the inventor had possession of the invention at the time the application was filed. *See Ralston Purina Co. v. Far-Mar-Co, Inc.* 772 F.2d 1570, 227 U.S.P.Q. 177 (Fed. Cir. 1985).

The written description requirement does not require the claims to correspond to the specific embodiments described in the Specification. Applicant is entitled to a broader scope of coverage if supported by the Specification. Applicant submits that the Specification supports the broad genus recited in the claims. It should be noted that the facts in *Regents of University of California v. Eli Lilly & Co.* are not entirely analogous to the instant case. In *Eli Lilly*, claims to genus of cDNAs encoding vertebrate insulin were rejected for lack of adequate written description support because the application only described the sequence rat cDNA. The application completely failed to provide a description for the cDNA encoding the human insulin.

In the instant case, the Specification describes two specific cDNAs that may be used in the invention (see Examples 2 and 3). The Specification also describes several other suitable nucleotide sequences from plants and bacteria that encode an ADP/ATP translocator that may be used in the invention. (see page 4, para. 2). Persons of ordinary skill in the art would be able to easily identify corresponding nucleotide sequences from other organisms using well-known techniques. The Specification also describes further functional features and a test for the functionality of an ATP/ADP translocator to select those foreign nucleic acid molecules suitable for use in the invention (see page 5, line 21 to page 6, line 24). A person of ordinary skill in the art after reviewing the Specification would reasonably believe that Applicant was in possession of the invention because the Specification describes several suitable foreign nucleic acid molecules for use in the invention and methods of identifying other suitable candidates. As

such, Applicant submits that the scope of the claims is fully supported by the Specification and requests that the rejection be removed.

B. Enablement

The Examiner has also rejected claims 1, 4-13 and 16 for lack of enablement. The Examiner acknowledges that the Application is enabled for a method for the production of transgenic potato plants transformed with the AATP1-cDNA gene from *Arabidoposis,* which exhibit an increased yield of starch and percent amylose content. However, the Examiner maintains that the application does not enable claims for a method for the production for transgenic plants transformed with a foreign nucleic acid molecule of undefined source, length and function, exhibiting an increased yield of starch and percent amylose content. The Examiner substantiates his rejection by relying upon Willmitzer et al. and Anderson, J. et al., which allegedly demonstrate the unpredictability inherent in attempting to engineer plants with increased and altered starch content using a transgenic approach. The Examiner also contends that undue trial and error would be needed to "isolate a multitude of non-exemplified foreign nucleic acid molecules from a multitude of sources" and to screen them to evaluate their ability to increase starch and amylose content in transformed plants. Applicants respectfully disagree.

The Examiner has argued that Willmitzer establishes the unpredictability of attempting to engineer a plant having increased and altered starch content using a transgenic approach. Willmitzer does generally describe the techniques developed to create transgenic plants and approaches to modify starch synthesis in potato tubers. Although Willmitzer's attempt to transform potato plants with a construct carrying a cDNA for a branching enzyme in anti-sense orientation did not affect the amylose content of the starch or the total starch content of the tubers, the Examiner has overlooked the fact that this reference also reports on the success achieved by Kishore et al. in increasing the starch content in tubers by expressing a form of E. Coli ADP-glucose phosphorylase (see page 37, para. 4). Anderson is cited for teaching that " . . . transformation with a single isoform of a starch metabolic enzyme gene is a highly unpredictable factor to consider in any attempt to modify gene expression using transgenic strategy". Applicant did not find any evidence of this teaching within the Anderson reference. There is no data in this reference relating to transgenic plants or any note

that gene regulation via a transgenic approach would not work. To the contrary, downregulation of the enzyme (ADP-glucose-pyrophosphorylase) discussed in the reference was later shown to lead to decreased starch levels in plants (see, e.g., Willmitzer, page 36, para. 5). Thus, the references cited by the Examiner tend to support the "predictability" of Applicant's approach.

Unlike Willmitzer and Anderson, the present application clearly demonstrates that the increase of ATP/ADP translocator activity leads to an increase of starch and an increase of the amylose content. As noted above, the Specification describes foreign nucleic acid molecules, which may be used to practice the invention and other suitable foreign nucleic acid molecules would be apparent to persons of ordinary skill in the art. The Examiner has attempted to argue that undue experimentation would be required to "isolate a multitude of non-exemplified foreign nucleic acid molecules from a multitude of sources" and to screen them to evaluate their ability to increase starch and amylose content in transformed plants. The fact that a large amount of experimentation may be necessary is not determinative.

Whether or not an application is enabled depends on whether the experimentation needed for practicing the invention is undue or unreasonable. Determining whether experimentation is undue often depends on the level of skill in the art and the kind of experimentation required to practice the invention. MPEP § 2164.01. Unquestionably, the level of skill in the field of molecular biology and biochemistry is high. Although the type of experimentation necessary to isolate orthologous DNA sequences as described on page 6 of the Office Action may be time consuming and repetitive, these experiments are routine and well within the abilities of the skilled artisan.

Applicant has described how to make and use the claimed invention and has set forth examples to demonstrate that the invention works. Applicant is not, however, required to describe each and every foreign nucleic acid molecule that may be used to practice the full scope of the invention. A person of ordinary skill in the art can isolate and identify suitable foreign nucleic acid molecules to practice the invention using conventional techniques without undue experimentation. As such, Applicant submits that the full scope of the claims are enabled and requests reconsideration and removal of the rejection.

6. Claim Rejections under 35 U.S.C. §102

Finally, the Examiner has rejected claims 1, 4-13 and 16 under 35 U.S.C. §102(b) as being anticipated by Barry et al. (WO 96/24679). Barry et al. teaches that the expression of sucrose phosphorylase in plants leads to an increase in starch levels. However, contrary to the Examiner's assumption, it cannot be said that Barry et al. inherently teaches "an increase in the plastidial ADP/ATP translocator activity in the transformed cells". The Examiner's conclusion is based on a faulty assumption, namely that " . . .the ATP/ADP translocator is rate limiting for starch biosynthesis". This conclusion is clearly contradicted by the teachings of the other references cited by the Examiner. Willmitzer teaches that ADP-glucose-pyrophosphorylase is the enzyme " . . . controlling the rate of starch biosynthesis" (see page 36, para. 5). Anderson similarly teaches that the "control of starch synthesis in leaf tissue occurs at a key enzymatic step catalyzed by ADP-glucose-pyrophosphorylase." (see page 159, para. 1 of the introduction and page 160, para. 3 which states that " . . . on the control of starch synthesis in tuber tissue at the level of ADP glucose pyrophosphorylase, the key regulatory enzyme in this process").

In view of these teachings, the only conclusion that can be drawn from Barry et al. is that the activity of an ADP-glucose-pyrophosphorylase is inherently increased upon expression of a *gtfA* gene in transgenic plants because the starch level was increased in these plants. Accordingly, Applicant submits that the Examiner's conclusion that the Barry et al. reference anticipates the claimed invention because it inherently teaches an increase in the plastidial ADP/ATP translocator activity is unfounded.

The Examiner has also argued that the Barry et al. reference anticipates the claimed invention because the level of starch in the transformed plants is inherently higher than the level of amylose. Applicant believes that the Examiner has not properly understood the invention. The increased amylose-content relates to the change in relative amount of amylose in the starch fraction (see page 8, para. 2 and page 16, para. 3 of the Specification). It does not relate to the "total" amount of amylose produced by the plants of the invention as calculated, for instance, with respect to the biomass of the respective plants. Applicant has amended the claim to clarify this point and would like to further emphasize that Barry et al. does not disclose particular feature. As such, Applicant submits that Barry et al. does not anticipate the claims.

Reconsideration and removal of the anticipation rejection in view of the Barry et al. reference is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Leonard R. Svensson (Reg. No. 30,330) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a one (1) month extension of time for filing a response in connection with the present application and the required fee of $110.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope to: Commissioner of Patents and Trademarks, Washington D.C. 20231 on: April 17, 2003
(Date of deposit)

BIRCH, STEWART, KOLASCH & BIRCH, LLP

Susan M. Farnsworthy
(Signature)

April 17, 2003
(Date of Signature)

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0147-0215P

Attachments: Claims as Amended
Drawings

Respectfully submitted,

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Claims

1. (Currently Amended) A genetically modified ~~transgenic~~ plant cell ~~which is genetically modified,~~ wherein a foreign nucleic molecule encoding a plastidial ADP/ATP translocator is integrated into the genome of said genetically modified plant cell ~~the genetic modification is an introduction of a foreign nucleic acid molecule whose~~ and wherein the ~~presence or~~ expression of said foreign nucleic acid molecule results ~~leads to~~ in an increase in ~~the~~ plastidial ADP/ATP translocator activity in comparison with corresponding non-genetically modified plant cells from wild type plants.

2. Cancelled (~~Withdrawn~~)

3. Cancelled (~~Withdrawn~~)

4. (Currently Amended) The genetically modified ~~transgenic~~ plant cell according to ~~any one of claims 1 to 3~~ claim 1 exhibiting an increased yield in comparison with corresponding non-genetically modified plant cells.

5. (Currently Amended) The genetically modified ~~transgenic~~ plant cell according to claim 1 exhibiting an increased oil ~~and/~~or starch content in comparison with corresponding nongenetically modified plant cells.

6. (Currently Amended) The ~~transgenic~~ genetically modified plant cell according to claim 1 synthesizing a starch fraction exhibiting an increased amylose-content in comparison with a starch fraction from corresponding non-genetically modified plant cells.

7. (Currently Amended) A ~~transgenic~~ genetically modified plant containing transgenic plant cells according to claim 1.

8. (Currently Amended) The ~~transgenic~~ genetically modified plant according to claim 7, which is an oil ~~and/~~or starch storing plant.

9. (Currently Amended) The ~~transgenic~~ genetically modified plant according to claim 8, which is a maize, rape, wheat or potato plant.

10. (Currently Amended) A method for the production of a transgenic plant exhibiting an increased yield in comparison with wild type plants, wherein

(a) a plant cell is genetically modified by ~~means of introduction of~~ integrating a foreign nucleic acid molecule encoding a plastidial ADP/ATP translocator into the genome of said plant cell wherein the ~~whose presence or~~ expression of said foreign nucleic acid molecule~~leads to~~results in an increase in ~~the~~ plastidial ADP/ATP translocator activity in the cell;

(b) a plant is regenerated from the cell produced according to step (a); and

(c) further plants are optionally produced from the plant produced according to step (b).

11. (Currently Amended) The method according to claim 10, wherein the transgenic plant exhibits an increased oil ~~and/~~or starch content in comparison with wild type plants and/or a~~whose~~ starch fraction ~~exhibits~~with an increased amylose content in comparison with a starch fraction from wild type plants.

12. (Original) A transgenic plant obtainable by the method according to claim 10 or 11.

13. (Currently Amended) Propagation material of genetically modified plants according to any one of claims 7 to 9 ~~or 12, wherein said propagation material contains transgenic cells according to claim 1~~.

Cancelled

14. (~~Withdrawn~~)

Cancelled

15. (~~Withdrawn~~)

16. (Previously Amended) A method for the production of a modified starch comprising the extraction of the starch from a plant according to any one of claims 7 to 9.

17. (New) The genetically modified plant cell according to claim 1 exhibiting an increased oil and starch content in comparison with corresponding non-genetically modified plant cells.

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18. (New) The method according to claim 10, wherein the transgenic plant exhibits an increased oil and starch content in comparison with wild type plants and a starch fraction with an increased amylose content in comparison with a starch fraction from wild type plants.

19. (New) The method according to claim 10, wherein the transgenic plant exhibits an increased oil and starch content in comparison with wild type plants or a starch fraction with an increased amylose content in comparison with a starch fraction from wild type plants.